Legislation on clinical trials

2112. SHRIMATI MOHSINA KIDWAI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether various women organizations in the country have demanded strengthening of legislation related to clinical trials of new drugs;

(b) if so, the details thereof;

(c) whether such organizations have raised concern over implementation of the good clinical practice guidelines and ethical norms; and

(d) if so, the steps Government propose to take to make the condition for clinical trials more stringent and introduce clear guidelines or compensation?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (c) The Drug Controller General (India) has informed that his office has not received any representation from women organizations in the country demanding strengthening of legislation related to clinical trials of new drugs. However, during deliberations among various stakeholders like industry associations, NGOs, experts, regulators etc. on the proposed amendment of Schedule Y to Drugs and Cosmetics Rules, some NGOs mentioned that Good Clinical Practice (GCP) guidelines and ethical norms should be strengthened and properly implemented in the country.

(d) Schedule Y already provides the requirements and guidelines for Clinical trials, which mandates that trial should be conducted as per GCP guidelines, Para 2.4.7 of GCP guidelines prescribes the provision for providing compensation by the sponsor in case of injury caused to the trial subjects. Schedule Y also prescribes responsibility of sponsor, investigator and ethics committee to safeguard the right safety and well being of the trial subjects. However, the following steps are under consideration of the office of Drug Controller General of India to make the condition for clinical trials more stringent:-

1. Good Clinical Trial Practice Inspection

2. Registration of Clinical Research Organization

3. Mandatory Clinical Trial Registration, which is currently advisory in nature.

Per head expenditure on health

2113. SHRI VIJAY JAWAHARLAL DARDA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government is aware of the WHO study pointing out that in India, the per head total expenditure is 91 US dollars and average surgical rate (for 1,00,000 population) is 369 dollars whereas in China it is 277 dollars and 2659 dollars respectively;

(b) if so, what was the financial allocations for health sector in 2006 and 2007 and whether these were fully utilized; and

(c) what is the per head allocation during 2008 for healthcare?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) Yes Sir.

(b) The budgetary allocation made by Ministry of Health and Family Welfare and extent of utilization of funds in respect of Health, NRHM and AYUSH during 2006-07 and 2007-08 is given in the table below:

(Rs. crore)

Year	Allocation (Plan and Non Plan)	Utilization (Plan and Non Plan)
2006-07	13009.15	11233.77
2007-08	15859.38	14393.19

(c) The budgetary allocation made by this Ministry towards health sector schemes (Plan and Non Plan) during 2008-09 is Rs. 18,123 crore and the projected population as per the Census of India for the year 2008 is 114.77 crore. Based on the above data, per head budgetary allocation by Govt. of India works out to Rs. 157.91

Allocation of funds to Himachal Pradesh under NRHM

2114. SHRIMATI VIPLOVE THAKUR: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what is the total amount of money allocated to Himachal Pradesh for financial year 2008-09 under National Rural Health Mission (NRHM);

(b) what is the total amount of money that has so far been utilized;

(c) whether Government has any mechanism to monitor whether the work is being carried out to achieve the goals of NRHM and the money allocated is being spent appropriately; and

(d) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) During Financial Year 2008-09, an amount of Rs.71.03 crores has been allocated to the State of Himachal Pradesh (HP) under National Rural Health Mission (NRHM). The State has reported utilization of an amount of Rs. 10.42 crore till 30th September, 2008.

(c) and (d) Under NRHM, a detailed framework for monitoring of the programme has been operationalised. This includes integrated web based Management Information System (MIS), which compiles progress of NRHM on key parameters at various levels. The results of periodic surveys like the District Level Household Surveys (DLHS), National Family Health Survey (NFHS) etc. also provide information about impact of various programme interventions. Periodic review missions are also undertaken to the States to monitor progress of the programme.